K061653

WEINMANN

5. 510(k) Summary

Weinmann SOYALA Full Face Mask

November 06, 2006

NOV - 9 2006

Submitter Information:

Weinmann
Gerate fur Medizin GmbH+Co. KG
Kronsaalsweg 40
22525 Hamburg / Germany

Submitter's Name:	Eckhardt Albers
Phone:	011 49 40 54 70 2 - 180
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Device Name:

Proprietary name:	Weinmann SOYALA Full Face Mask
Common Name:	Face mask
Classification Name:	Accessory to non-continuous ventilator

Device Classification:

21 CFR 868.5905, Class II, Product Code BZD

Predicate Device Equivalence:

Substantial equivalence is claimed to ResMed Mirage Full Face Mask Series 2, cleared for commercial distribution per K023244, Weinmann SOMNO*mask*, K013738, Weinmann SOYALA, K060405, and Fisher & Paykel Flexifit Series HC431 Full Face Mask, K040506.

Device Description:

The SOYALA Full Face Mask is a molded plastic face mask covering the patient's nose and mouth and including an exhalation system, for the delivery of CPAP or Bi-level Positive Pressure therapy.

It consists of a mask cushion, mask frame, forehead cushion, coarse adjustment component, fine adjustment component, forehead support, headgear, headgear clip, ports for pressure measurement, port cap, rotating sleeve, elbow with anti asphyxia valve, and retaining ring.

The mask provides a swivel and securely attached elbow connection for simple and secure handling of the tubing between the mask and the therapy device.

The Weinmann SOYALA Full Face Mask comes in three sizes, small, medium and large. It has a removable mask cushion.

An anti-asphyxia valve is integrated into the elbow of the mask. It functions as a safety mechanism, which allows the patient to breathe fresh air if the therapy device ceases operation.

SOYALA Full Face Mask is secured to the patient's head with a 4-point headgear called the SOYALA*strap*. An alternate headgear model is also available.

Intended Use:

The SOYALA Full Face Mask is intended for adult patients (>30kg) prescribed continuous positive airway pressure (CPAP) or bi-level therapy for multiple-patient use in a hospital or clinic environment after high-level disinfection and for single-patient use in a home environment.

Comparison of Technological Characteristics

The Weinmann SOYALA Full Face Mask has the same technological characteristics as the predicate device.
The new device has the following similarities to the previously cleared predicate device:

- Same intended use
- Same operating principle
- Same technology
- Same manufacturing process

Some materials of the new device are different from the predicate device. The changed materials represent secondary support or incidental contact. Safety and effectiveness are not affected by these changes.

Summary of Device Testing:

Bench testing was performed to ensure that the SOYALA Full Face Mask met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

Conclusion:

Based on the above, we concluded that the Weinmann SOYALA Full Face Mask is substantially equivalent to the legally marketed predicate device and is safe and effective for its intended use, and performs as well as or better than the predicate device.

End of section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2006

Mr. Eckhardt Albers
Quality Assurance Manager
Weinmann Gerate Fur Medizin GmbH + Company KG
Kronsaalsweg 40
Hamburg
GERMANY 22525

Re: K061653
Trade/Device Name: SOYALA Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: October 17, 2006
Received: October 24, 2006

Dear Mr. Albers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061653

Device Name: SOYALA Full Face Mask

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

n of Anesthesiology, General Hospital,
ion Control, Dental Devices
K061653